K131007

510(k) Summary

JUL 10 2013

In accordance with 21 CFR 807.92, TYRX, Inc. provides this summary of the safety and effectiveness information available for AIGISRx® N, as well as the substantial equivalence decision making process used for the AIGISRx N subject device.

Sponsor/Applicant Name and Address:	TYRX, Inc. 1 Deer Park Drive Monmouth Junction, NJ 08852
Establishment Registration Number:	3005619263
Sponsor Contact Information:	Susan Olinger Vice President, Regulatory Affairs Phone: 732.964.1110 Fax: 732.964.1490 Email: solinger@tyrx.com Alternate Contact: Regina Novak Manager, Regulatory Affairs Phone: 732.964.1492 Fax: 732.964.1490 Email: rnovak@tyrx.com
Date of Preparation of 510(k) Summary:	April 11, 2013
New Device Trade/Proprietary Name:	AIGISRx® N
Device Common/Classification Name:	Surgical Mesh, Class II PROCODE: FTL
Predicate Device Name and 510(k) Number	AIGISRx® (K063091)

Device Description:

AIGISRx® N is a dual component (resorbable and non-resorbable) sterile prosthesis designed to hold a vagus nerve stimulator securely to create a stable environment when implanted in the body. It is constructed of knitted filaments of polypropylene that are coated with a bioresorbable polyarylate polymer containing the antimicrobial agents

rifampin and minocycline. Rifampin and minocycline have been shown to reduce infection in an *in vivo* model of bacterial challenge following surgical implantation of an implantable electronic device.

Device Intended Use:

AIGISRx® N is intended to hold a vagus nerve stimulator securely in order to create a stable environment when implanted in the body. AIGISRx ®N contains the antimicrobial agents rifampin and minocycline which have been shown to reduce infection in an *in vivo* model of bacterial challenge following surgical implantation of the pulse generator or defibrillator. This device is only intended to be used in conjunction with vagus nerve stimulators implanted in the infraclavicular fossa or anterolateral abdominal wall.

Technological Characteristics:

The physical, chemical, and mechanical properties of the AIGIS N subject device, such as mesh knit characteristics, suture retention strength, tear strength and burst strength are the same as the AIGISRx® predicate device. There is no change to the design, materials of construction, or manufacturing processes for the subject device. There are no technological differences between the subject and predicate devices, and there are no design changes to the predicate device.

Performance Data:

AIGIS N is designed to be a biocompatible, sterile device intended to hold a vagus nerve stimulator securely in order to create a stable environment when implanted in the body. The AIGIS N subject device is identical to the AIGIS predicate device. Information on the cleared predicate device, K063091, is included by reference in this 510(k).

AIGIS is sterile, biocompatible, and non-pyrogenic. Sterility conforms to ISO 11137, and bench testing shows that gamma sterilization has no detrimental effect on the chemical structure or thermal properties of the polypropylene substrate mesh. Standard ISO 10993 testing demonstrated the biocompatibility and safety of the device. An *in vivo* functionality study showed that AIGIS devices do not alter or interfere with an implantable pacemaker or defibrillator.

Conclusions:

Both the AIGISRx predicate and AIGISRx N subject devices are safe and effective for their intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 10,2013

TYRX Inc.
Susan Olinger
1 Deer Park Drive
Monmouth Junction, NJ, 08852

Re: K131007
Trade/Device Name: AIGISRx N
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: April 11, 2013
Received: April 11, 2013

Dear Ms. Olinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K131007**

Device Name: **AIGISRx N Antibacterial Envelope**

Indications For Use:

AIGISRx® N is intended to hold a vagus nerve stimulator securely in order to create a stable environment when implanted in the body. AIGISRx® N contains the antimicrobial agents rifampin and minocycline, which have been shown to reduce infection in an in vivo model of bacterial challenge following surgical implantation of a pulse generator or defibrillator. This device is only intended to be used in conjunction with vagus nerve stimulators implanted in the infraclavicular fossa.

Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.07.10 18:51:02 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K131007